REMARKS

Upon entry of this amendment, claims 5-10, 12-14, 30, 33 and 42-48 will be pending. Claims 19 and 39 have been canceled without prejudice or disclaimer as drawn to non elected subject matter. Applicant reserves the right to pursue these claims in a later application. Claim 10 has been amended. Support for claims can be found in the specification and claims as originally filed. No new matter has been added.

Information Disclosure Statement

Applicant has provided herewith a corrected Information Disclosure Statement providing full citation information for references previously considered incomplete.

Rejection under 35 U.S.C. §101

Claims 5-10, 12-14, 30, 33 and 42-48 are rejected under 35 U.S.C.§101 as allegedly not supported by either a substantial asserted utility or a well established utility.

Applicant respectfully disagrees. Applicants have asserted such a utility for the claimed invention in the specification. For example, in Example 3 beginning at page 151 of the specification, the expression of genes of the invention in a variety of normal and pathology-derived cells, cell lines and tissues were assessed quantitatively by real time quantitative PCR (RTQ PCR). Results for NOV 8, nucleic acid encoding SEQ ID NO:20, are found at pages 207-214 and are summarized at pages 213-214. More specifically, for example, the specification teaches:

> **Panel 1.3D Summary** Ag2251 The highest level of expression of the NOV8 gene is seen in a CNS cancer cell line SK-N-AS (CT=29.6). The gene is also expressed at higher levels in cell lines derived from lung, prostate, and breast cancers compared to the normal tissues and may play a role in these cancers. Thus, expression of the NOV8 gene could be used as a marker or as a therapeutic for lung, prostate and breast cancer. (page 213 lines 2-5)
>
> **Panel 2D Summary** Ag2251 The highest expression of NOV8 gene is seen in a breast cancer sample (CT = 30.3). The expression of this gene appears to show an association with samples derived from colon, lung, kidney, breast, bladder and gastric

> cancers when compared to the matched normal tissue. Thus, expression of the NOV8 gene could be used as a marker for these cancers. Page 214 lines3-7

One of skill in the art, having read the specification, would therefore know to detect and compare the amount of expression of the nucleotide encoding SEQ ID NO:20 in such samples, by using, e.g. RTQ-PCR methods as described in the specification to differentiate malignant tissue, particularly colon, lung, kidney, breast, bladder and gastric cancers, from normal tissue.

The asserted utility is specific and substantial. Applicants have not suggested that NOV8 be used in a general undefined way or for diagnosing an unspecified disease. The specification teaches that the nucleic acid encoding the polypeptide of SEQ ID NO:20 may be used as a specific target for detecting expression, particularly, for example in colon, lung, kidney, breast, bladder and gastric cancers, and therefore is useful to differentiate specific malignant tissue from normal tissue. Applicant's asserted utility has a "real world" context. Furthermore, the specification teaches that not any nucleic acid but specifically NOV 8 may be used in these types of samples for this purpose. Since Applicants have made an assertion that the claimed invention is useful for a particular purpose, and such assertion would be considered credible by a person of ordinary skill in the art, a rejection based on lack of utility is not proper. Applicants respectfully request that the rejection of claims 5-10, 12-14, 30, 33 and 42-48 under 35 U.S.C. §101 be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 5-10, 12-14, 30, 33 and 42-48 are rejected under 35 U.S.C. §112 first paragraph as allegedly not supported by a substantial or a well-established utility. Applicants respectfully disagree. As discussed above, the specification clearly describes how to use the claimed invention and provides at least one asserted specific, substantial and credible utility. Therefore, Applicants respectfully submit that this rejection should be withdrawn.

Rejections under 35 U.S.C. § 112, second first paragraph

Claim 10 is rejected under 35 U.S.C. §112 second paragraph as allegedly indefinite for the recitation: "hybridized under stringent conditions".

Applicant disagrees with the Examiner's position. However in order to expedite prosecution of the present subject matter, Applicant has amended claim 10 to clarify the hybridization conditions as comprising "a high salt buffer comprising 6X SSC, 50 mM Tris-HCl (pH 7.5), 1 mM EDTA, 0.02% PVP, 0.02% Ficoll, 0.02% BSA, and 500 mg/ml denatured salmon sperm DNA at 65°C." Support for this amendment can be found in the specification as filed at page 87, line 34 to page 88 line 2. As such, Applicant believes claim 10 to be clear and respectfully requests the rejection of claim 10 under 35 U.S.C. §112 second paragraph be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph, written description

Claim 10 is rejected under 35 U.S.C. §112 first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner contends that "one skilled in the art cannot envision the full genus of molecules of the claimed polyeptide (sic) molecules. The claims encompass variants whose structure is not known or other variant proteins with different function from SEQ ID NO:20.

Applicant respectfully disagrees. Claim 10 pertains to an isolated nucleic acid molecule comprising a nucleic acid sequence which hybridizes under stringent conditions comprising a high salt buffer comprising 6X SSC, 50 mM Tris-HCl (pH 7.5), 1 mM EDTA, 0.02% PVP, 0.02% Ficoll, 0.02% BSA, and 500 mg/ml denatured salmon sperm DNA at 65°C to a nucleotide molecule encoding a polypeptide comprising an amino acid sequence SEQ ID NO: 20. As such, the claim pertains to a polynucleotide, not protein. It is an elementary exercise for one of skill in the art to define the nucleic acid sequence that would encode SEQ ID NO:20. One of skill in the art would further know how to carry out the experiment to determine specific polynucleotides and their sequence that would successfully hybridize under the defined conditions recited in the claim. Therefore the structure of the *polynucleotide* encompassed by the claim is known or can be readily determined by one of skill in the art.

The Examiner relies on the decision of University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997) to support this rejection. In University of California v. Eli Lilly, the court held that a patent specification which includes by example a process for obtaining human insulin-encoding cDNA, and which describes the protein (amino acid sequence) that the cDNA encodes, but which does not describe the structure of the claimed cDNA in terms of its nucleotide sequence, does not comply with the written description requirement of 35 U.S.C. §112, first paragraph. However, in contrast to the situation in University of California v. Eli Lilly, Applicant *has* described the structure of the claimed nucleotide sequence that encodes SEQ ID NO:20, for example, SEQ ID NO:19 in the present specification. Other examples including, SEQ ID NO:21, 23 and 25 are also provided. The University of California v. Eli Lilly court also held that the cDNA nucleotide sequence for rat insulin, as described by the patentee, did not provide a written description adequate to claim the genus of vertebrate or mammalian insulin cDNA. Applicant does not claim the genus of vertebrate or mammalian proteins based upon Applicants description of human NOV8. Applicant has claimed the defined set of nucleotide sequences having specific physical properties that allow for specific hybridization, under specific high stringency conditions to the further defined set of nucleotide sequences that specifically encode the specific protein sequence SEQ ID NO:20. Applicant's description is not "a mere wish or plan for obtaining the claimed chemical invention" as in the University of California v. Eli Lilly case. Furthermore, as acknowledged by the court, a description of a genus of cDNA's may be achieved by means of a recitation of a representative number of cDNA's, defined by nucleotide sequence, falling within the scope of the genus. Therefore Applicant respectfully submits that claim 10 is sufficiently described in the specification and furthermore requests that the rejection of claim 10 under 35 U.S.C. §112 first paragraph be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph, new matter

Claims 42-48 are rejected under 35 U.S.C. §112 first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner contends that the specification does not disclose the claim limitations of claims 42-48.

Applicant respectfully submits that support for claims 42-48 can be found in the specification as filed at page 63 line 21 to page 64 line 1, Table 8I which describes single nucleotide polymorphic (SNPs) variants of NOV8, specifically: a base change of T to C at consensus position 227; C to T at position 482; A to G at position 523; G to A at position 548; G to A at position 573; and T to C at position 684. Applicant requests that the rejection of claims 42-48 under 35 U.S.C. §112 first paragraph be withdrawn.

Rejection under 35 U.S.C. § 102

Claim 10 is rejected under 35 U.S.C. §102(b) by the Examiner as anticipated by Stripp et al. The Examiner contends Stripp discloses a nucleic acid encoding a protein which is 83% similar to the claimed polypeptide of SEQ ID NO:20.

Applicants disagree. Stripp et al discloses a rat nucleic acid sequence which is 81% similar to Applicant's SEQ ID NO: 19. However, claim 10 pertains to a sequence which *hybridizes* (i.e. the complement or reverse transcript) to a nucleic acid sequence that encodes Applicant's protein SEQ ID NO:20. As such the polynucleotide of claim 10 is not anticipated by the disclosure of Stripp and the rejection of claim 10 under35 U.S.C. §102(b) should be withdrawn.

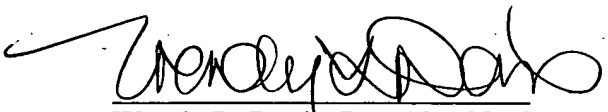
The Examiner further states that claims 30, 32-35, 74, 89, 91-94 and 116 are rejected under 35 U.S.C. 102(e) as anticipated by Meadows et al. As Applicants claims number 5-10, 12-14, 30, 33 and 42-48, and Meadows is not cited on the Examiner's Notice of References Cited, Applicant suspects that this may be a typographical error and respectfully requests the Examiner clarify any indented rejection based upon Meadows.

CONCLUSION

Applicants respectfully request that the amendments and remarks made herein be entered and made of record in the file history of the present application. Applicants respectfully submit that this paper is fully responsive to the Restriction Requirement of June 28, 2004, and that the pending claims are in condition for allowance. Such action is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact

the undersigned at the telephone number provided below.

Respectfully submitted,



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